PROCESS FOR ESTABLISHING A SET OF RADIOLOGICAL, NUCLEAR, AND PROCESS SAFETY STANDARDS AND REQUIREMENTS FOR TWRS PRIVATIZATION

U.S. Department of Energy Richland Operations Office

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Preface

As noted below, the DOE regulatory approach for the radiological, nuclear, and process safety regulation of the TWRS Privatization Contractor is described in an integrated set of four documents, which should be read in the order listed below to obtain an understanding of the regulatory approach. The DOE regulatory approach to radiological, nuclear, and process safety clearly places on the Contractor the responsibility to achieve adequate safety, comply with applicable laws and legal requirements, and conform to top-level safety standards and principles stipulated by DOE. According to a prescribed process, DOE interacts with each Contractor in arriving at DOE decisions to approve and authorize Contractor activities. The DOE maintains a continuing interaction with the Contractor to ensure that the Contractor is meeting the safety conditions of its contract and the conditions of the DOE approvals; is complying with applicable laws and legal requirements; and is conforming to the DOE-stipulated top-level safety standards and principles.

Consistent with applicable laws and legal requirements, the requirements applied to each Contractor are tailored to control the hazards specific to the activities of that Contractor. With knowledge and understanding of the hazards specific to its activities, each Contractor is required to identify and recommend for DOE approval a set of safety standards to which the Contractor certifies, that when properly implemented, will ensure for that Contractor's activities 1) adequate safety, 2) compliance with applicable laws and legal requirements, and 3) conformance to DOE-stipulated top-level safety standards and principles. When DOE approves the set of Contractor-recommended safety standards, the set together with the DOE-stipulated top-level safety standards and principles becomes the requirements which are applied to the Contractor's activities.

The four documents that describe the DOE regulatory approach for the radiological, nuclear, and process safety regulation of TWRS Privatization Contractors are:

- Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0005; Revision 0,
- 2. DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0003; Revision 0,
- Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors, DOE/RL-96-0006; Revision 0, and
- Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization, DOE/RL-96-0004; Revision 0.

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1.0 Purpose

The purpose of this document is to describe the process that the TWRS Privatization Contractor shall use to develop and recommend a set of radiological, nuclear, and process safety standards and requirements. Employing this process will produce a standards set, to be recommended by the Contractor Representative for approval consideration by the Director of the DOE Regulatory Unit, that will serve as a basis for issuance of an approved Safety Requirements Document (SRD), as a condition of the Contract. The approved SRD sets forth the requirements with which the Contractor's activities must comply. The SRD shall also contain, as a subset, the nuclear safety requirements that are enforceable under 10 CFR 820.

The process described herein will allow the Contractor and the Regulatory Unit to accomplish the first of six regulatory actions for the radiological, nuclear, and process safety regulation of the TWRS Privatization Contractors. The details of this regulatory process are provided in the document titled *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors* (DOE/RL-96-0003, 1996).

2.0 Background

DOE intends to afford the Contractor significant flexibility in the exercise of the Contractor's responsibility to identify safety standards and requirements. Properly implemented, these standards and requirements provide:

- 1) Adequate safety;
- 2) Compliance with applicable laws and regulations (specifically DOE nuclear safety regulations 10 CFR 820, 10 CFR 830, 10 CFR 834, and 10 CFR 835); and
- 3) Conformance to top-level safety standards and principles stipulated within the DOE document titled, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors* (DOE/RL-96-0006, 1996).

This concept of the Contractor's role in the identification of safety standards and requirements that apply to its activities is consistent with *Criteria for the Department's Standards Program* (DOE/EH/-0416, 1994). DOE's Standards Program includes the following essential functions:

- 1) Identification of applicable standards;
- 2) Justification of the adequacy of the applicable standards;
- 3) Implementation of applicable standards;
- 4) Administrative and management processes and infrastructure that support, deliver, and demonstrate standards-based work; and
- An integrated approach to management of performance, independent of the source of the standard.

The process described in this document as applied to TWRS Privatization addresses the first two essential functions.

There are seven Essential Process Steps included within the process for standards set identification for TWRS Privatization. Within these steps, as appropriate to TWRS Privatization, the concepts of *The Department of Energy Closure Process For Necessary and Sufficient Sets of Standards* (DOE M 450.3-1, 1996) have been applied.

3.0 Standards Process Description

This section describes the process that shall be used by the Contractor to produce a set of recommended radiological, nuclear, and process safety standards. A key feature of this process is that these standards for performance of work link directly to specific radiological, nuclear, and process hazards associated with that work. Additionally, the use of experts and participation by stakeholders will ensure credibility, completeness, and adequate protection of workers, the public, and the environment. Figure 1 (Section 4.0) depicts the Essential Process Steps, and shows that DOE has responsibility for providing the input and approving the output from the process, while the Contractor has responsibility for employing the process.

3.1 Steps of the Process

Table 1 lists the steps of the process necessary to develop a recommended set of radiological, nuclear, and process safety standards. The Essential Process Steps listed in the first column shall be performed by the Contractor to ensure that the process is performed in a manner consistent with DOE's Standards Program. The second column identifies the individuals or groups of individuals who should perform these essential steps. The third column provides an approach for accomplishing each step that is acceptable to the DOE Regulatory Unit. Although the Contractor Representative may deviate from the Acceptable Approach, the Contractor Representative shall assure that the process used meets the concepts of DOE M 450.3-1.

3.2 Stakeholder Input and Views

This process described herein invites and encourages stakeholders to express their views and provide input to the maximum extent possible, while recognizing the need to protect the proprietary information of the Contractor. Stakeholder input and views are important to ensuring the overall integrity and fidelity of the process, as well as the qualifications of the process performers. Although a stakeholder cannot be a member of the process management or the independent review teams, the Contractor Representative shall invite and encourage stakeholders to individually express their views and provide input in steps 1 and 5, i.e., process initiation and standards confirmation. Further guidance for the Contractor Representative on obtaining stakeholder input can be obtained in *The Department of Energy Closure Process For Necessary and Sufficient Sets of Standards* (DOE M 450.3-1, 1996).

3.3 Contractor's Recommendation and Certification

The recommendation of the standards set by the Contractor Representative to the Director of the Regulatory Unit constitutes a two-fold certification:

- 1) That the set, when properly implemented, will ensure adequate radiological, nuclear, and process safety, compliance with applicable laws and regulations, and conformance to the DOE-stipulated top-level standards and principles, and
- 2) That this process was employed with integrity.

Table 1. Process to Develop Standards

ESSENTIAL	PERFORMERS	ACCEPTABLE APPROACH
PROCESS		
STEP 1. Process	• CR	CR designates PM and PMT
Initiation		CR provides charter and delegates authority to PM and PMT to implement this standards process
	• PM	 PM prepares implementation plan including team staffing requirements, team operating procedures, outputs required, documentation required
		PM prepares rosters (candidates & credentials)
	• PMT	 PMT approves plans, rosters, and procedures PM mobilizes the process activities
	Stakeholders	Stakeholders invited and encouraged to provide input and express views to PM and PMT
	• RMRU	RMRU attends any meetings that will facilitate
		early gathering of information on process
2. Identification	• PM	 PM manages the Step-2 activities
of Work	• DC	DC provides technical/contractual scope support
	• WAE	WAE define overall processes
		WAE identify and describe key systems,
		structures, components, and operations • WAE document the work activities
	• PMT	PMT provides technical resource consultation
	- FWH	PM proposes additional experts as needed
		PMT approves additional experts as needed
		PMT monitors the Step-2 activities
	• RMRU	• RMRU attends any meetings that will facilitate
		early gathering of information on process
3. Hazards	• PM	PM manages the Step-3 activities
Evaluation	• WAE	WAE provide consultation on work elements
	• HAE	HAE identify and describe work hazards
		HAE define a hazard assessment approach
		HAE assess work hazards
		HAE document the hazards assessment
		PMT provides technical resource consultation
		PM proposes additional experts as needed
	• PMT	PMT approves additional experts as needed
	D. W.	• PMT monitors the Step-3 activities
	• RMRU	RMRU attends any meetings that will facilitate
		early gathering of information on process

Acronyms:

CR = Contractor Representative IRT = Independent Review Team

DC = DOE Customer PM = Process Manager

ESE = ESH Standards Experts PMT = Process Management Team

HAE = Hazards Assessment Experts RMRU = Review Manager from Regulatory Unit

HCE = Hazards Control Experts WAE = Work Activity Experts

Table 1 (continued). Process to Develop Standards

ESSENTIAL	PERFORMERS	ACCEPTABLE APPROACH
PROCESS STEP		
4. Identification of Standards	• PM • WAE • HAE • HCE • ESE	 PM manages the Step-4 activities WAE provide consultation on work elements HAE provide consultation on work hazards HCE delineate hazards control approaches ESE select appropriate standards based on the Step 2 & 3 results and hazards control approaches ESE prepare justifications of standards selections and identify any legal requirements and top-level standards and principles that do not add value
	• PMT	 ESE/PM document the set of selected standards PMT provides technical resource consultation PM proposes additional experts as needed PMT approves additional experts as needed PMT monitors the Step-4 activities
	• RMRU	RMRU attends any meetings that will facilitate early gathering of information on process
5. Confirmation of Standards	• PM • CR	 PM manages the Step-5 activities CR designates the IRT PM facilitates IRT activities by providing documentation, information briefings, and discussion meetings
	• IRT	 IRT defines its review/confirmation approach IRT performs its review IRT documents its approach and findings IRT provides comments to the PM for revision of the set of selected standards and associated documentation
	PMTStakeholdersRMRU	PMT monitors the Step-5 activities Stakeholders invited and encouraged to provide input and express views to PM and PMT RMRU attends any meetings that will facilitate
	KWIKU	early gathering of information on process
6. Formal Documentation	• PMT • PM	PMT verifies the overall process implementation PM prepares draft of submittal required by Director of the Regulatory Unit (Safety Requirements Document and supporting information) PMT reviews the draft submittal PM recommends final submittal to CR CR approves the final submittal
7. Recommendation by CR	• CR	CR certifies the set of standards contained in the final submittal is adequate and provides submittal to Director of the Regulatory Unit

Acronyms:

CR = Contractor Representative IRT = Independent Review Team

DC = DOE Customer PM = Process Manager

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HAE = Hazards Assessment Experts RMRU = Review Manager from Regulatory Unit

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4.0 Figure

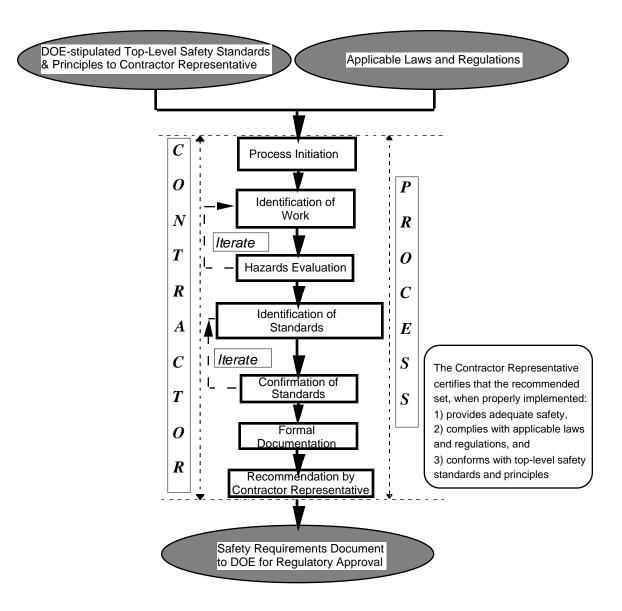


Figure 1. Process Steps to Develop Recommended Set

5.0 Glossary*

<u>Acceptable Release</u>. The release of radioactive material, within acceptable limits, to the environment.

<u>Anticipated Operational Occurrences</u>. Conditions of normal operation expected to occur one or more times during the life of the facility and include, but are not limited to, loss of off-site power to the process activity within the facility.

<u>Authorization Agreement</u>. The document mutually agreed upon by the Director of the Regulatory <u>Unit and a regulated Contractor that specifies authorization terms and conditions.</u>

<u>Authorization Basis</u>. The composite of information provided by a Contractor in response to radiological, nuclear, and process safety requirements that is the basis on which the Director of the Regulatory Unit grants permission to perform regulated activities.

<u>Back-fit</u>. The addition, elimination, or modification of 1) structures, systems, or components of the facility or 2) procedures or organizations required to operate the facility after the operating authorization has been issued.

<u>Catastrophic Release</u>. A major uncontrolled emission, fire, or explosion involving one or more highly hazardous chemicals that presents serious danger to employees in the workplace.

<u>Co-located Worker</u>. An individual within the Hanford Site, beyond the Contractor-controlled area, performing work for or in conjunction with DOE or utilizing other Hanford Site facilities.

<u>Common-Cause Failures</u>. Dependent failures that are caused by a condition external to a system or set of components that make system or multiple component failures more probable than multiple independent failures.

<u>Common-Mode Failures</u>. Dependent failures caused by susceptibilities inherent in certain systems or components that make their failures more probable than multiple independent failures due to those components having the same design or design conditions that would result in the same level of degradation.

<u>Contractor(s)</u>. The private company(ies) selected to contract with DOE for construction and operation of the technologies and facilities necessary to retrieve, process tank waste, and deliver treated waste products to DOE for storage or disposal.

<u>Contractor Representative (CR)</u>. The top manager of the Contractor Organization that has direct responsibility, accountability, and authority for performing the TWRS Privatization work subject to the set of standards.

Contractor-recommended set of standards and requirements. Those standards and requirements identified through a DOE-specified process and recommended by the Contractor Representative as necessary assurance that work will be performed in a manner that protects the workers, the public, and the environment from the actual hazards identified for the Contractor's specific work activities. (Also see the definition for "Requirements.") The recommended set serves as a basis for DOE review and approval by the Director of the Regulatory Unit, and the Contractor's issuance of the Safety Requirements Document.

* Certain terms used in this document and listed in this glossary have origins in radiological and nuclear safety. Extension of their use to process safety may be useful but is not stipulated herein. It is expected that the extension of their use to process safety will be considered as part of the standards and requirements identification process.

<u>Controlled Area</u>. The physical area enclosing the facility by a common perimeter (security fence). Access to this area can be controlled by the Contractor. The controlled area may include identified restricted areas.

<u>Deactivation Safety Evaluation Report</u>. The document approved and issued by the Director of the Regulatory Unit that addresses the adequacy of the authorization basis for deactivation.

<u>Defense in Depth.</u> The fundamental principle underlying the safety technology of the facility centered on several levels of protection including successive barriers preventing the release of radioactive materials to the workplace or environment. Human aspects of defense in depth are considered to protect the integrity of the barriers, such as quality assurance, administrative controls, safety reviews, operating limits, personnel qualification and training, and safety program. Design provisions, including both those for normal facility systems and those for systems important to safety help to: 1) prevent undue challenges to the integrity of the physical barriers; 2) prevent failure of a barrier if it is challenged; 3) where it exists, prevent consequential damage to multiple barriers in series; and 4) mitigate the consequences of accidents. Defense in depth helps to assure that two basic safety functions (controlling the process flow and confining the radioactive material) are preserved and that radioactive materials do not reach the worker, public, or the environment.

<u>Design Basis</u>. The information that identifies the specific functions to be performed by structures, systems, or components of the facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design.

<u>Design-Basis Events</u>. Postulated events providing bounding conditions for establishing the performance requirements of structures, systems, and components that are necessary to: 1) ensure the integrity of the safety boundaries protecting the worker; 2) place and maintain the facility in a safe state indefinitely; or 3) prevent or mitigate the event consequences so that the radiological exposures to the general public or the workers would not exceed appropriate limits. The Design-Basis Events also establish the performance requirements of the structures, systems and components whose failure under Design-Basis Event conditions could adversely affect any of the above functions.

<u>Director of the Regulatory Unit (DRU)</u>. An individual who has been delegated the authority to execute the radiological, nuclear, and process safety regulation of TWRS Privatization Contractors.

<u>DOE-Customer</u>. A DOE employee who has knowledge of the equipment, facilities, and processes-necessary for performance by the Contractor of the work activities to deliver the contracted services.

ESH Standards Experts (ESE). Individuals with knowledge and expertise relevant to the radiological, nuclear, or process standards and requirements in a particular environment, safety, and health discipline.

<u>Facility</u>. Those buildings and equipment directed to a common purpose and those activities and supporting elements occurring at a single location.

<u>Final Safety Evaluation Report</u>. The document approved and issued by the Director of the Regulatory Unit that addresses the adequacy of the authorization basis for operation.

<u>Hazard</u>. A source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to personnel, damage to an operation, or to the environment (without regard for the likelihood or credibility of accident scenarios or consequence mitigation).

<u>Hazards Assessment Experts (HAE)</u>. Individuals with the knowledge, skills and abilities to identify, based on examination of the work activities defined, the hazards associated with the

work activities, as well as the risk to the workers, public and environment attributable to those hazards.

<u>Hazards Control Experts (HCE)</u>. Individuals with knowledge, skills and abilities to identify, based on examination of the work activities and associated hazards, the controls necessary to mitigate the hazards to an acceptable level.

<u>Highly Hazardous Chemical</u>. A substance possessing toxic, reactive, flammable, or explosive properties as defined by 29 CFR 1910.119.

Important to Safety. Structures, systems, and components that serve to provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the workers and the public. It encompasses the broad class of facility features addressed (not necessarily explicitly) in the top-level radiological, nuclear, and process safety standards and principles that contribute to the safe operation and protection of workers and the public during all phases and aspects of facility operations (i.e., normal operation as well as accident mitigation).

This definition includes not only those structures, systems, and components that perform safety functions and traditionally have been classified as safety class, safety-related or safety-grade, but also those that place frequent demands on or adversely affect the performance of safety functions if they fail or malfunction, i.e., support systems, subsystems, or components. Thus, these latter structures, systems, and components would be subject to applicable top-level radiological, nuclear, and process safety standards and principles to a degree commensurate with their contribution to risk. In applying this definition, it is recognized that during the early stages of the design effort all significant systems interactions may not be identified and only the traditional interpretation of important to safety, i.e., safety-related may be practical. However, as the design matures and results from risk assessments identify vulnerabilities resulting from non-safety-related equipment, additional structures, systems, and components should be considered for inclusion within this definition.

<u>Independent Oversight</u>. Authorized oversight by bodies or groups having no financial, programmatic, or other direct interest in the activities or organizations under review and which are totally free of management relationships with those activities or organizations.

<u>Independent Oversight Bodies</u>. Independent Oversight Bodies are those established organizations that have no financial, programmatic, or other direct interest in and are outside the management structure of the Contractor and the Regulatory Unit. The independent oversight bodies include personnel qualified and skilled to critique, evaluate, and recommend that the regulatory oversight provided by the Regulatory Unit of the Contractor is effective.

<u>Independent Review Team (IRT)</u>. A group of individuals with the appropriate knowledge and expertise to review the recommended standards set for completeness, credibility, and adequacy before the standards are recommended by the Contractor Representative to the Director of the Regulatory Unit.

<u>Initial Safety Evaluation Report</u>. The document, approved and issued by the Director of the Regulatory Unit, that addresses the capability or potential for obtaining future authorizations for construction, operation, and deactivation.

<u>Integrated Safety Management Plan (ISMP) Evaluation Report.</u> The document, approved and issued by the Director of the Regulatory Unit, that addresses the adequacy of the Contractor's Integrated Safety Management Program as reflected in its Integrated Safety Management Plan.

<u>Integrated Safety Management Program.</u> A set of integrated activities that is directed toward the management or control of radiological, nuclear, and process hazards such that adequate protection is provided to workers, the public, and the environment.

<u>Limiting Conditions for Operations (LCO)</u>. The lowest functional capability or performance level of equipment required for safe operation of the facility.

<u>Limiting Control Settings (LCS)</u>. The settings for automatic alarm or protection devices related to those variables having significant safety functions.

Margin of Safety. The level of confidence that is assigned to the integrity of radiological control measures such as confinement barriers. It is defined as the range between the design acceptance limits and the design failure point of the control feature. The design acceptance limits for radiological control measures such as confinement barriers are established during the design of the facility. These criteria are given in terms of those physical parameters that define their performance. Whenever the values of the design acceptance limits are exceeded, the margin of safety, and therefore the confidence in the integrity of the control feature, is decreased.

Normal Operation. Steady-state operation and those departures from steady-state operation that are expected frequently or regularly in the course of facility operation, system testing, and maintenance. It includes conditions such as startup, shutdown, standby, anticipated operational occurrences, operation with specific equipment out of service as permitted by the approved operational constraints, and routine inspection, testing, and maintenance of components and systems during any of these conditions if it is consistent with the approved operational constraints.

Off-site. The area outside the perimeter of the Hanford Site.

On-site. The area within the Hanford Site control perimeter, which is under the jurisdiction of DOE.

Oversight Safety Determination. The oversight of the Contractors performed by the Regulatory Unit to ensure continuing compliance to an authorization agreement.

<u>Postulated Accidents</u>. Events, including the design-basis events, that would have an adverse affect on the facility process but which do not have a significant probability of occurrence during the life of the facility and include, but are not limited to, pipe or tank failures.

Preliminary Safety Evaluation Report. The document, approved and issued by the Director of the Regulatory Unit, that addresses the adequacy of the authorization basis for construction.

<u>Process</u>. Any activity involving a highly hazardous chemical including use, storage, manufacturing, handling, or the on-site movement of such chemicals, or a combination of these activities.

<u>Process Manager (PM)</u>. A person, designated by the Contractor Representative, responsible for <u>ensuring that the Process Steps</u> are accomplished.

<u>Process Management Team (PMT)</u>. A group of individuals designated by the Contractor Representative to approve specified actions proposed by the Process Manager and to monitor their implementation.

<u>Process Safety</u>. The operation of facilities that handle, use, process, or store hazardous materials in a manner free of episodic or catastrophic incidents. However, the handling, use, processing, and storage of materials with inherent hazardous properties can never be done in the total absence of risk. Process safety is an ideal condition towards which one strives.

<u>Process Safety Management</u>. The application of management systems to the identification, understanding, and control of process hazards to prevent process-related injuries and incidents.

Public. Individuals who are not occupationally engaged at the Hanford Site.

<u>Radiation Worker</u>. A worker who has qualifications and training to work in a restricted area of the facility where radiation or radioactive material is present.

<u>Regulatory Unit</u>. The organization reporting to the Director of the Regulatory Unit dedicated to supporting the Director in executing regulatory authority.

Reliability Targets. Quantified probabilistic expectations that a component, equipment, or system will perform its intended function satisfactorily under given circumstances, such as environmental conditions, limitations as to operation time, and frequency and thoroughness of maintenance for a specified period of time. Identified important to safety items are expected to perform their function satisfactorily through all design basis accident conditions.

<u>Requirements</u>. Standards that are mandated by an authority through statute, regulation, or contract.

<u>Restricted Area.</u> An area identified by the Contractor to which access is limited for the purposes of protecting individuals against undue risk from exposure to radiation and radioactive materials. Only a radiation worker is allowed into this area.

<u>Risk Analysis</u>. The development of a qualitative or quantitative estimate of risk based on engineering evaluation and techniques for considering estimates of incident consequences and frequency.

<u>Safe State</u>. A situation in which the facility process has been rendered safe and no pressurized material flow occurs in the process lines. Any active, energy generating, process reactions are in controlled or passive equipment. The structures, systems, and components necessary to reach and maintain this condition are functioning in a stable manner, with all process parameters within normal safe state ranges.

<u>Safety Analysis Report (SAR)</u>. A document that fully describes the analyzed safety basis for the facility (safety envelope), fully demonstrates that the facility will perform and will be operated such that radiological, nuclear, and process safety requirements are met, and fully demonstrates adequate protection of the public, the workers, and the environment.

<u>Safety Assurance</u>. Established confidence that adequate protection of worker and public health and safety has been provided.

<u>Safety Basis</u>. The combination of information relating to the control of hazards at a nuclear facility (including design, engineering analyses, and administrative controls) upon which the Director of the Regulatory Unit depends for its conclusion that activities at the facility can be conducted safely.

<u>Safety Function</u>. Any function that is necessary to ensure: 1) the integrity of the boundaries retaining the radioactive materials; 2) the capability to place and maintain the facility in a safe state; or 3) the capability to prevent or mitigate the consequences of facility conditions that could result in radiological exposures to the general public or workers in excess of appropriate limits.

<u>Safety Limits</u>. Limits on process variables associated with those physical barriers, generally passive, that are necessary for the intended facility safety functions and that are found to be required to prevent release of unacceptable levels of radioactive material to workers or the general public.

<u>Safety Requirements Document (SRD)</u>. A document that contains the approved and mandated set of radiological, nuclear, and process safety standards and requirements which, if implemented, provides adequate protection of workers, the public, and the environment against the hazards associated with the operation of the Contractor's facilities.

<u>Safety Requirements Document Evaluation Report</u>. The document approved and issued by the Director of the Regulatory Unit that addresses the adequacy of the set of radiological, nuclear, and process safety standards that a Contractor proposes to implement to ensure adequate protection of worker and public health and safety.

<u>Safety Setpoints</u>. Physical parameters set in the control equipment by an operator for equipment that controls the process or process flow to maintain the process within the systems design safety limits. A safety set-point represents a process characteristic, such as pressure, temperature, or material level, that is monitored by a control system to restrict the process characteristic within a system's design operating range. These set-points, identified in the design as levels above which a process physical parameter would exceed a design operating range of a process component or system leading to its failure and risk to the safety of the worker, public, or the environment. Several may be used to initiate alarm levels or control the process to a safe state.

<u>Significantly New Safety Information</u>. Either: 1) a safety requirement newly mandated by the Regulatory Unit; 2) a safety item newly identified by the Contractor as an item not included in the SAR for the facility; or 3) a determination that an unresolved safety question exists.

<u>Stakeholder</u>. Any individual other than Federal employees or DOE contractor employees that will be materially affected by, or can materially affect, the outcome of the work, either favorably or unfavorably.

Standards. The expressed expectation for the performance of work.

<u>State-of-the-Art Human Factors</u>. The most effective design approaches established for use at the <u>start of the final design phase</u>.

<u>Technical Safety Requirements</u>. Those requirements that define the conditions, the safe boundaries,

and the management or administrative controls necessary to ensure the safe operation of the facility, reduce the potential risk to the public and facility workers from uncontrolled releases of radioactive materials, and from radiation exposures due to inadvertent criticality.

<u>Unreviewed Safety Question (USQ)</u>. A safety question where any of the following conditions are satisfied: 1) the probability of occurrence or the radiological consequences of an accident or malfunction of equipment important to safety, previously evaluated in the facility safety analyses or other related safety analysis and evaluations not yet included in the updated facility analysis, may be increased; 2) a possibility for an accident or equipment malfunction of a different type than any evaluated previously in the facility safety analyses or other related safety analysis and evaluations not yet included in the updated facility safety analysis, may be created; or 3) any margin of safety is reduced. (Also see definition for "Margin of Safety.")

<u>Worker</u>. Worker means an individual within the controlled area of the facility performing work for or in conjunction with the Contractor or utilizing Contractor facilities.

<u>Work Activities</u>. All activities associated with performing the work, including design, construction, operation, and deactivation.

<u>Work Activity Experts</u>. Individuals with knowledge and expertise relevant to the work, site, and activities addressed by the standards set.